

BENIGN PROSTATIC HYPERPLASIA TREATMENTS**Effective Date: November 1, 2024****Review Dates: 8/24****Date of Origin: Aug 14, 2024****Status: New**

Note: This policy includes content from the following previously separate policies: Urolift/Prostatic Urethral Lift (#91613); Prostatic Artery Embolization for Benign Prostatic Hyperplasia (#91620); Prostatic Urethral Lift & Transurethral Water Vapor Therapy For BPH (#91626);

I. POLICY/CRITERIA**A. The following approaches to the treatment of benign prostatic hypertrophy (BPH) are medically necessary:**

1. Holmium Laser Enucleation of the Prostate (HoLEP), Thulium laser enucleation of the prostate (ThuLEP)
2. Simple prostatectomy (Open, laparoscopic, or robotic assisted) when InterQual criteria are met.
3. Photoselective vaporization of the prostate (PVP)
4. Transurethral incision of the prostate (TUIP)
5. Transurethral Resection of the Prostate (TURP)
6. Transurethral vaporization of the prostate (TUVP)

B. Prostatic Artery Embolization

1. **PAE** may be medically necessary for benign prostatic hyperplasia (BPH) when *all* of the following are met:
 - a. Evaluation and referral by a urologic surgeon
 - b. Moderate to severe lower urinary tract symptoms (LUTS)
 - c. Refractory to at least 6 months of medical therapy
 - d. Prostate volume too large (>80 cc) for transurethral procedure
 - e. Poor surgical candidate for open prostatectomy
 - f. Prostate Specific Antigen (PSA) <2.5 ng/mL, or PSA >2.5 ng/mL and ≤10 ng/mL AND free PSA > 25% of total PSA
2. Prior authorization for imaging prior to PAE is required. A computed tomographic angiography (CTA) of the pelvis is medically necessary for PAE when indicated if the above criteria are met.
3. PAE is not considered medically necessary if any of the following are present:
 - a. Active prostatitis or urinary tract infection
 - b. Cystolithiasis within the past 3 months
 - c. History of prior pelvic irradiation
 - d. History of prostate, bladder, or rectal cancer

- e. History of transurethral resection of the prostate (TURP), open prostate surgery, or radiofrequency or microwave therapies of prostate.
 - f. Serum creatinine values >1.7mg/dl or glomerular filtration rates less than 50.
 - g. Confounding bladder or urethral conditions (e.g. neurogenic bladder, urethral stricture)
4. PAE for all other conditions is considered experimental and investigational and/or not medically necessary.

C. Prostatic urethral lift

1. The UroLift System is medically necessary for the treatment of symptomatic benign prostatic hypertrophy (BPH), including lateral and median lobe hyperplasia, when **both** of the following criteria are met:
 - a. Men age 45 and older, and
 - b. Prostate volume $\leq$ 100 cc
2. Urolift is not medically necessary if *any* of the following are present:
 - a. Active urinary tract infection
 - b. Gross hematuria
 - c. Prostate volume of >100 cc
 - d. Urethral conditions that may prevent insertion of delivery system into bladder.
 - e. Urinary incontinence due to incompetent sphincter

Coverage is limited to a maximum of seven (7) implants.

D. The Rezūm System is medically necessary for the reduction of prostate tissue associated with BPH, and for treatment of prostate with hyperplasia of the central zone and/or a median lobe when both of the following criteria are met:

1. Men age 50 and older, and
2. Prostate volume $\geq$ 30 cc and $\leq$ 80 cc
3. The Rezūm System is not indicated for patients with a urinary sphincter implant or penile prosthesis.

E. Transurethral Waterjet Ablation

1. Transurethral Waterjet Ablation of the prostate for the treatment of LUTS/BPH will be considered medically necessary when all of the following are met:
 - a. Prostate volume of 30-150 cc transrectal ultrasound (TRUS)
 - b. Persistent moderate to severe symptoms despite maximal medical management including ALL of the following:
 - i. International Prostate Symptom Score (IPSS) $\geq$ 12

- ii. Maximum urinary flow rate (Qmax) of ≤ 15 mL/s (voided volume greater than 125 cc)
 - iii. Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
 - iv. Device must be FDA approved or cleared device.
2. Transurethral waterjet ablation of the prostate is not considered medically necessary if any of the following are present:
- a. Body mass index ≥ 42 kg/m²
 - b. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) > 10 ng/mL unless the member has had a negative prostate biopsy within the last 6 months.
 - c. Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum
 - d. Active urinary tract or systemic infection
 - e. Treatment for chronic prostatitis
 - f. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
 - g. Damaged external urinary sphincter
 - h. Known allergy to device materials
 - i. Inability to safely stop anticoagulants or antiplatelet agents preoperatively.

F. The following approaches for the treatment of BPH experimental or investigational and unproven, or not medically necessary because the clinical effectiveness has not been established by the peer-reviewed medical literature:

- 1. Optilume drug coated balloon for BPH
- 2. Permanent urethral stent (e.g. UroLume endourethral prosthesis)
- 3. Transrectal thermal therapy
- 4. Transurethral microwave thermotherapy (TUMT)
- 5. Transurethral needle ablation of the prostate (TUNA)
- 6. Temporary implanted prostatic devices (i.e. temporary prostatic stents, Spanner)

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the [Priority Health Provider Manual](#).

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. BACKGROUND

Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement or growth of the prostate. As the prostate enlarges, the gland presses against and pinches the urethra and the bladder wall becomes thicker. Eventually, the bladder may weaken and lose the ability to empty completely, leaving some urine in the bladder. The narrowing of the urethra and urinary retention—the inability to empty the bladder completely—cause many of the problems associated with benign prostatic hyperplasia. The cause of benign prostatic hyperplasia is not well understood; however, it occurs mainly in older men (NIDKK, 2014).

Holmium Laser Enucleation (HoLEP) and Thulium Laser Enucleation (ThuLEP)

Endoscopic enucleation of the prostate (EEP) is a method of removing excess prostate tissue that contributes to BPH symptoms. Several energy sources have been used to aid enucleation, including holmium:yttrium-aluminum-garnet (Ho:YAG), thulium:YAG (Thu:YAG), and other lasers, as well as monopolar and

bipolar electrocautery. Ho:YAG and Thu:YAG lasers remain among the energy sources most commonly applied for EEP.

Holmium laser enucleation of the prostate (HoLEP) was initially described by Gillig et al in 1998. The energy of the Ho:YAG laser is transmitted in pulses, creating a steam bubble at the tip of the laser fiber, which aids mechanical dissection. HoLEP has been proven to be at least equivalent to TURP in terms of improving (LUTS) and voiding parameters while being superior in the amount of tissue removed. In comparison to open prostatectomy, the rate of transfusion, hemoglobin loss, length of stay (LOS), and catheter time are reduced, while improvements in the maximum flow rate (Qmax) and LUTS are comparable.

The Thu:YAG laser transmits energy as a continuous wave. Its wavelength is close to 2.0 μm , the peak for water absorption, which thus facilitates vaporization and cutting. Thulium laser enucleation of the prostate (ThuLEP) was described by Herrmann et al in 2010 as an evolution of thulium laser vapoenucleation of the prostate (ThuVEP) described by Bach et al in 2009. In theory, ThuLEP uses blunt dissection to a greater extent than ThuVEP, where mainly the incising capacity of the laser is utilized. In clinical practice, a combination of the two techniques is usually performed and a clear distinction is not feasible. The cutting ability may be advantageous in situations in which the enucleation plane cannot easily be entered, as anatomical enucleation is not strictly necessary. By contrast, HoLEP is generally considered to be more anatomical, as the mechanical energy of the laser tends to follow the path of least resistance, which is usually the plane between the adenoma and the surgical capsule.

In a meta-analysis by Hartung et al (2021) comparing HoLep versus ThuLEP, the authors found that both treatments offer comparable improvement in symptoms and postoperative voiding parameters. Both procedures are safe and major complications are rare. ThuLEP showed minor advantages for blood loss and the incidence of transient incontinence. Treatment choice should be based on surgeon expertise and local conditions.

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the clinician’s expertise with these techniques, as prostate size-independent options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer laser enucleation of the prostate using Ho:YAG laser (HoLEP) to men with moderate-to-severe LUTS as an alternative to transurethral resection of the prostate or open prostatectomy [strength rating: strong]”
- “Offer enucleation of the prostate using the Tm:YAG laser (ThuLEP, ThuVEP) to men with moderate-to-severe LUTS as an alternative to transurethral resection of the prostate, holmium laser enucleation or bipolar transurethral (plasmakinetic) enucleation [strength rating: weak]” (Cornu et al, 2024).

Optilume Drug Coated Balloon for BPH

The Optilume® BPH Catheter System (Urotronic Inc., Plymouth, Minnesota, USA) is the first prostatic drug-coated balloon dilation system for the treatment of obstructive BPH. The system combines mechanical dilation to achieve commissurotomy of the anterior prostatic urethra to open the urethral lumen, with the delivery of the drug paclitaxel to the dilated area to maintain urethral patency. Paclitaxel is an antiproliferative drug that has been extensively used in vascular devices to prevent restenosis after balloon angioplasty or stenting. The goal of this technology is to provide immediate symptomatic relief via balloon dilation and to achieve durable results via localized paclitaxel delivery. In the PINNACLE study, A total of 148 men were randomized (100 active, 48 sham) at 18 centers in the U.S. and Canada. Subjects randomized to receive Optilume BPH saw a reduction in International Prostate Symptom Score of 11.5 ± 7.8 points at 1 year posttreatment, as compared to a reduction of 8.0 ± 8.3 points at 3 months in the sham arm. Flow rate was dramatically improved after treatment with Optilume BPH, with an improvement of $+10.3$ mL/s from baseline to 1 year ($+125\%$). (Kaplan et al., 2023). More studies evaluating long-term safety and efficacy of this treatment are needed.

Temporary Implanted Prostatic Devices (i.e. Temporary Prostatic Stents)

Temporary implanted prostatic devices are intended to provide temporary relief from symptoms of BPH caused by prostatic obstruction. These devices include but are not limited to iTind (temporary implanted nitinol device) and The Spanner temporary prostatic stent. The iTind treatment involves insertion of a single folded device into the prostatic urethra. The device expands and exerts continuous gentle ischemic pressure on the prostatic urethra and the bladder neck over 5-7 days, causing ischemic necrosis and creating channels that allow for increased urine flow. The device is then removed in a second outpatient procedure. (Kernen et al., 2023)

The Spanner stent is mounted on an insertion device and advanced along the urethral meatus and pendulous urethra until the tip is within the bladder. The Spanner system utilizes a balloon which is then inflated with 5 mL of sterile water and seated in the bladder neck. The distal anchor is deployed distal to the external

sphincter and the insertion tool is removed from the urethra. (McKenzie et al., 2011) In contrast to iTind, the Spanner can remain in place for up to 30 days before requiring removal and re-insertion. In an FDA investigational device exemption (IDE) study by Cambio and colleagues (2022), The Spanner was placed for 3 cycles of 30 days in catheter-dependent men with comorbid conditions, confirmed detrusor contractility, and catheter-associated discomfort. At each visit, postvoid residual, maximum flow rate, international prostate symptom score, quality of life, and adverse events were assessed. Voiding success was defined as PVR $\leq$ 150 ml at all visits. One hundred seven men were enrolled at 8 US sites; 82/107 (76.6%) completed the trial, and 79/107 (73.8%) successfully maintained PVR $\leq$ 150 ml for the trial duration. Patients were 77.1 ± 10.6 years old; 63/107 (58.9%) were dependent on Foley and 40/107 (37.4%) on intermittent catheterization for 36.0 ± 39.3 days and 30.2 ± 45.8 days, respectively. 25/107 (23.4%) discontinuations were primarily due to voluntary patient withdrawal 9/107 (8.4%), investigator-initiated withdrawal 8/107 (7.5%), or lack of effectiveness 4/107 (3.7%). During Spanner use, the mean Qmax was 11.2 ± 6.6 , mean IPSS was 7.5 ± 6.4 , and mean QOL was 2.0 ± 1.6 . The most prevalent device-related adverse events were asymptomatic bacteriuria 25/107 (23.4%), discomfort 10/107 (9.4%), and urinary urgency 8/107 (7.5%). No device-related serious adverse events were reported. There is a lack of high-quality systematic reviews and meta-analyses to confirm safety and efficacy of temporary implanted prostatic devices.

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “TIPD may be offered as a treatment option for patients with LUTS/BPH provided prostate volume is between 25 and 75g and lack of obstructive median lobe. (Expert Opinion)” (Sandhu et al, 2023)

Permanent Urethral Stent (UroLume Endourethral Prosthesis)

The UroLume prostatic stent is a woven tubular mesh consisting of erosion-resistant wire that was designed specifically for use within the urethra. During a cystoscopy procedure, a calibrated balloon catheter is used to measure the prostatic length. Once the appropriate length is determined, the stent is deployed into the prostatic urethra and the expansile force of the mesh holds it in position. The intent of the device is that the epithelium will grow over the stent, covering it entirely while maintaining patency of the prostatic urethra. (Yip et al., 1997) The device originally received FDA approval for use in urethral strictures, and more recently approval has expanded to include BPH; however there is not sufficient evidence for safety and efficacy of this device for the indication of BPH. In a systematic review by Armitage and colleagues, a total of 20 case series were

included which evaluated the UroLume stent in a total of 990 patients with benign prostatic hyperplasia. 84% who were catheter dependent voided spontaneously after stent insertion. Ten studies assessed symptoms before stent insertion and at some point within 1 year after stent insertion. All reported decreases in symptom scores, including Madsen-Iversen by 7.9 to 14.3 points and International Prostate Symptom Score by 10 to 12.4 points. Peak urine flow rates increased by 4.2 to 13.1 ml per second. A total of 104 stents (16%) failed in 606 patients who were evaluable at 1 year and migration was the commonest cause of failure (38 stents or 37%). Most patients initially experienced perineal pain or irritative voiding symptoms following stent placement. 1 of 6 men needed the UroLume removed within a year because of complications. Inadequate followup prevented conclusions on stent durability beyond 1 year. (Armitage et al, 2007)

Photoselective Vaporization of the Prostate (PVP)

Photoselective vaporization of the prostate (PVP) with the GreenLight laser™ (GLL) (American Medical Systems, Minnetonka, USA) is a minimally invasive method of treating BPH. The first generation machines (60 W and 80 W) used a potassium-titanyl-phosphate crystal to double the frequency of a Nd:YAG laser, emitting a 532-nm wavelength, delivered to tissues by a side-firing fiber and producing a vaporization effect due to a very high absorption coefficient at this wavelength by its target chromophore that is hemoglobin molecule. This high energy density delivered to the prostatic tissue leads to rapid vaporization of the superficial tissue with a small rim of coagulated tissue. The new generation machines use a lithium-triborate crystal that allowed an increase in the maximum power output of the GLL from 80 W to 180 W. Moreover, new fibers have been introduced, resulting in even higher energy application and faster tissue vaporization via a larger laser beam area. As a result, GLL has become the preferred surgical technique to manage patients who cannot stop anticoagulation/antiplatelet therapy (Castellani et al., 2021). Meta-analyses of RCTs comparing photoselective vaporization of the prostate (PVP) using the 80-W and 120-W lasers with TURP have reported no difference in Qmax and IPSS between 80-W or 120-W PVP and TURP. Another meta-analysis of four RCTs including 559 patients, on the 120-W laser, demonstrated no significant difference in functional and symptomatic parameters at 24-month follow-up when compared to TURP. A meta-analysis of two RCTs reported similar efficacy of 120-W PVP, compared to monopolar transurethral resection of the prostate (M-TURP) at 36-months follow-up. The only available RCT for the 180-W laser reported non-inferiority to TURP in terms of IPSS, Qmax, PVR, prostate volume reduction, PSA decrease and QoL questionnaires. Efficacy outcomes were similar to TURP with stable results at 24-months follow-up (Cornu et al, 2024).

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer 80-W 532-nm Potassium-Titanyl-Phosphate (KTP) laser vaporization of the prostate to men with moderate-to-severe LUTS with a prostate volume of 30-80 mL as an alternative to transurethral resection of the prostate (TURP) [strength rating: strong]”
- “Offer 120-W 532-nm Lithium Borate (LBO) laser vaporization of the prostate to men with moderate-to-severe LUTS with a prostate volume of 30-80 mL as an alternative to TURP. [strength rating: strong]”
- “Offer 180-W 532-nm LBO laser vaporization of the prostate to men with moderate-to-severe LUTS with a prostate volume of 30-80 mL as an alternative to TURP. [strength rating: strong]”
- “Offer laser vaporization of the prostate using 80-W KTP, 120- or 180-W LBO lasers for the treatment of patients receiving antiplatelet or anticoagulant therapy with a prostate volume < 80 mL [strength rating: weak]” (Cornu et al., 2024).

Prostatic Artery Embolization (PAE)

PAE is a minimally invasive procedure for benign prostatic hyperplasia (BPH) to improve lower urinary tract symptoms (nocturia, hesitancy, urgency, frequency, decreased urinary flow, incomplete emptying) by decreasing the prostate volume. The procedure is offered as an alternative to transurethral resection of the prostate (TURP) or open prostatectomy. PAE selectively occludes small prostatic arteries and deprives the enlarged prostate of blood supply and nutrients. This leads to ischemic necrosis and shrinkage of the affected section of the prostate gland. The procedure is performed using a percutaneous transfemoral approach by an interventional radiologist under local anesthesia and sedation. The arterial occlusion may be achieved through the use of polyvinyl alcohol particles, coil embolizers, or microspheres.

In June 2017, the FDA granted Embosphere Microspheres additional 510(k) clearance for embolization of prostatic arteries (EPA) for symptomatic benign prostatic hyperplasia (BPH), making it a prostatic artery embolization device. Embosphere Microspheres are currently indicated for use in embolization of arteriovenous malformations, hypervascular tumors, including symptomatic uterine fibroids, and prostatic arteries for symptomatic BPH.

In four RCT (Gao, 2014; Carneval, 2016; Abt 2018 Insausti 2020) studies comparing PAE to TURP found PAE was associated with statistically significant improvement in some or all measures of LUTS and a measure of erectile function. In a RCT comparing PAE to placebo Pisco et al. (2020) found PAE is somewhat better than TURP for perioperative outcomes but consistently inferior to TURP for improving symptoms of BPH. PAE resulted in clinically significant improvement in IPSS and IPSS Quality of Life (IPSS-QoL) and statistically significant improvement in BPH Impact Index (BII), peak urinary flow, postvoid residual urine volume, prostate volume, and PSA level. In other studies comparing pretreatment with posttreatment, PAE was associated with statistically significant improvement in some or all of these outcome measures and a measure of erectile function. A systematic review and meta-analysis to evaluate PAE vs TURP for BPH (Xu, 2021) concluded that TURP is more effective than PAE for reducing prostate volume and increasing peak urinary flow but that PAE is more effective for preserving sexual function. Differences between PAE and TURP in IPSS, IPSS-QoL, PVR, PSA level, and complications were not significant.

The Society of Interventional Radiology (SIR) guidelines (McWilliams, 2019) concluded that PAE is an acceptable option for treatment of appropriately selected male persons who have BPH and moderate to severe symptom with good short- and midterm durability. The American Urological Association guidelines (Sandhu, 2023) on the management of BPH with LUTS states that PAE may be offered for the treatment of LUTS/BPH. PAE should be performed by clinicians trained in this interventional radiology procedure. The panel was unable to find substantial evidence to recommend PAE over more widely available minimally invasive therapies for the routine treatment of LUTS, but there is evidence showing a short-term benefit of PAE compared to observation in a very select patient population. PAE is a technically demanding procedure, averaging fluoroscopy times of up to 50 minutes and procedure times up to 2 hours.

Guidelines

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “PAE may be offered for the treatment of LUTS/BPH. PAE should be performed by clinicians trained in this interventional radiology procedure following a discussion of the potential risks and benefits. (Conditional Recommendation: Evidence level: Grade C)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer prostatic artery embolization (PAE)* to men with moderate-to-severe LUTS who wish to consider minimally invasive treatment options and accept less optimal outcomes compared with transurethral resection of the prostate. [strength rating: weak]”

- “Perform PAE only in units where the work up and follow-up is performed by urologists working collaboratively with trained interventional radiologists for the identification of PAE suitable patients. [strength rating: strong]” (Cornu et al., 2024)

The Rezūm System (Boston Scientific)

Rezūm is a minimally invasive, transurethral water vapor therapy treatment for lower urinary tract systems (LUTS) due to benign prostatic hyperplasia (BPH). Rezūm utilizes convective radiofrequency (RF) water vapor energy to ablate hyperplastic tissue. Water vapor energy ablation to treat BPH tissue delivers RF generated thermal therapy using convection, the movement from a steam source of heated fluid carrying energy.

The Rezūm System consists of a radiofrequency power generator and a disposable delivery device. The rigid shaft of the delivery device incorporates a standard lens so that the procedure may be performed under cystoscopic visualization. The delivery device also contains a needle, which injects steam into diseased prostatic tissue. The steam immediately condenses to water thereby dispersing thermal energy and killing the surrounding cells. The dead cells are eventually absorbed, which reduces the volume of prostatic tissue and opens the urethra. The goal is to create contiguous, overlapping lesions approximately 1 cm apart along the urethra.

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “Water Vapor Thermal Therapy (WVTT) should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g. (Moderate Recommendation; Evidence Level: Grade C)”
- “WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Randomised controlled trials against a reference technique are needed to confirm the first promising clinical results and to evaluate mid- and long-term efficacy and safety of water vapor energy treatment.” (Cornu et al., 2024)

Simple Prostatectomy – Open, Laparoscopic, or Robotic-Assisted

Open prostatectomy (OP) is the oldest surgical treatment for moderate-to-severe LUTS secondary to benign prostate obstruction (BPO) (EAU, 2024). Obstructive

adenomas are enucleated using the index finger, approaching from within the bladder (Freyer procedure) or through the anterior prostatic capsule (Millin procedure). It is used for substantially enlarged glands (> 80-100 mL). The term minimal invasive simple prostatectomy (MISP) includes laparoscopic simple prostatectomy (LSP) and robot-assisted simple prostatectomy (RASP). Both LSP and RASP are performed using different personalized techniques, based on the transcapsular (Millin) or transvesical (Freyer) approach.

A systematic review (SR) and meta-analyses of MISP showed that in 27 observational studies including 764 patients mean increase in Qmax was 14.3 mL/s, and the mean improvement in IPSS was 17.2. There were no differences in improvements in Qmax and IPSS. A meta-analysis comparing MISP vs. OP reported no significant differences with regard to functional and symptom parameters between the two techniques. A multicenter RCT with median follow-up of 26 months did not demonstrate any significantly different functional or perioperative results between LSP, RASP and HoLEP. A SR and meta-analysis of five non-randomized comparative trials comparing RASP with LSP demonstrated a shorter length of hospital stay after RASP as well as a higher post-operative Qmax. An RCT comparing HoLEP versus MISP for large volume (≥ 120 mL) prostate glands resulted in longer catheterization time in the LSP group than RASP and HoLEP groups ($p=0.002$). Furthermore, MISP resulted in longer hospitalisation, and lower rate of patients with new-onset of storage LUTS. (Cornu et al., 2024).

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “Open, laparoscopic, or robotic assisted prostatectomy should be considered as treatment options by clinicians, depending on their expertise with these techniques, only in patients with large to very large prostates. (Moderate Recommendation; Evidence Level: Grade C) (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer open prostatectomy in the absence of anatomical endoscopic enucleation of the prostate to treat moderate-to-severe LUTS in men with prostate size > 80 mL [strength rating: strong]”
- “Minimal invasive simple prostatectomy is feasible in men with prostate sizes > 80 mL needing surgical treatment; however, RCTs are needed.” (Cornu et al., 2024)

Transurethral Incision of the Prostate (TUIP)

Transurethral incision of the prostate (TUIP) involves incising the bladder outlet without relevant tissue removal. Transurethral incision of the prostate is conventionally performed with Collins knife using electrocautery; however, alternative energy sources such as holmium laser may be used. The mainstay of this technique is in prostate sizes < 30 mL without a middle lobe. An RCT comparing conventional TUIP vs. TUIP using holmium laser in prostates ≤ 30 mL with a follow-up of twelve months, found both procedures to be equally effective in relieving BOO with similarly low re-operation rates. A meta-analysis of ten RCTs found similar LUTS improvements and lower but significant improvements in Qmax for TUIP. In this meta-analysis, an upper limit of prostate size was reported as an entry criterion for eight studies with five < 30 mL and three < 60 mL. A meta-analysis of six trials showed that re-operation was more common after TUIP (18.4%) than after M-TURP (7.2%) (Cornu et al., 2024).

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “TUIP should be offered as an option for patients with prostates ≤ 30 g for the surgical treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer transurethral incision of the prostate to surgically treat moderate-to-severe LUTS in men with prostate size < 30 mL, without a middle lobe. [strength rating: strong]” (Cornu et al., 2024)

Transurethral Resection of the Prostate (TURP)

Transurethral resection of prostate (TURP) has been the gold standard technique for surgical treatment of benign prostate hyperplasia (BPH) over the last several decades. Monopolar transurethral resection of prostate (M-TURP) is performed by passing high frequency current from a generator through an active electrode, allowing for electroresection of the prostate. Irrigation is used to provide a clear vision for the surgeon to continue resection of the vascular prostate. Bipolar transurethral resection of prostate was introduced in the early 2000s as an alternative to M-TURP. Bipolar technology uses high frequency energy to create a vapor layer of plasma which contains energy-charged particles that induce tissue disintegration through molecular dissociation. As the active and return electrode are placed on the same axis of the resectoscope, high current densities are achieved locally and distant negative effects reduced. The reduction in lower resection temperature compared to conventional monopolar systems theoretically reduces thermal damage to surrounding tissue (Teo et al., 2017).

Guidelines:

American Urological Association – *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “TURP should be offered as a treatment option for patients with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)”
- “Clinicians may use a monopolar or bipolar approach to TURP as a treatment option, depending on their expertise with these techniques. (Expert Opinion)” (Sandhu et al, 2023)

-

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer bipolar- or monopolar-transurethral resection of the prostate to surgically treat moderate-to-severe LUTS in men with prostate size of 30-80 mL [strength rating: strong]” (Cornu et al., 2024).

Transurethral Needle Ablation of the Prostate (TUNA)

Transurethral needle ablation of the prostate is an alternative surgical therapy for BPH that uses low energy radiofrequency delivered into the prostatic adenoma in the lateral lobes of the prostate, causing heat-induced coagulation necrosis. (Issa, 1996). TUNA is recognized as a “legacy technology” by the American Urological Association, which acknowledges that this procedure has largely been replaced by newer minimally invasive technologies.

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “The panel recognizes several “legacy technologies” that have been historically used, and are currently FDA approved, but have very limited newly published data to be able to comment on their efficacy. The panel has observed that with newer minimally invasive technologies these “legacy technologies” are largely being displaced. The panel recognizes transurethral microwave thermotherapy of the prostate (TUMT) and transurethral needle ablation of the prostate (TUNA) as two of these legacy technologies, therefore guideline statement referencing these “legacy technologies” have been removed.”

Transrectal Thermal Therapy/Transurethral Microwave Thermotherapy (TUMT)

Thermotherapy for treatment of BPH can be delivered via transrectal or transurethral routes. Transrectal thermal therapy has been largely replaced by

transurethral microwave thermotherapy (TUMT). TUMT devices deliver relatively high microwave energy to the prostate, heating prostatic tissue to produce coagulation necrosis. With most devices the transurethral microwave antenna is contained within a cooling catheter to prevent urethral thermal injury. (Hoffman et al., 2003). TUMT is recognized as a “legacy technology” by the American Urological Association, which acknowledges that this procedure has largely been replaced by newer minimally invasive technologies.

Transurethral Vaporization of the Prostate (TUVP)

Bipolar transurethral vaporization of the prostate (B-TUVP) utilizes a bipolar electrode and a high-frequency generator to create plasma field (thin layer of highly ionized particles) to vaporize prostatic tissue. Bipolar transurethral vaporisation of the prostate displays thinner (< 2 mm) coagulation zones, compared to monopolar TUVP (up to 10 mm), potentially resulting in fewer irritative side-effects and stress urinary incontinence (SUI). Bipolar-TUVP has been compared to TURP in thirteen RCTs, including a total of 1,244 men with a prostate size of < 80 mL. Early RCTs evaluated the PK B-TUVP system; however, during the last decade, only the “plasma” B-TUVP system with the “mushroom- or button-like” electrode (Olympus Medical) has been evaluated. Results have been pooled in three meta-analyses and a narrative synthesis has been produced in two SRs. Follow-up in most RCTs is twelve months with the longest being 36 months in a small RCT (n = 40) and eighteen months in a subsequent RCT (n = 340); evaluating PK and plasma B-TUVP, respectively. Results from meta-analyses concluded that no significant differences exist in short term efficacy (IPSS, QoL score, Qmax and PVR) between PK B-TUVP and TURP. This was confirmed in a separate SR of seven RCTs. Higher quality RCTs with longer follow-up are necessary to draw definite conclusions on mid and long-term outcomes (Cornu et al., 2024).

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “Bipolar TUVP may be offered as an option to patients for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer bipolar transurethral vaporization of the prostate as an alternative to transurethral resection of the prostate to surgically treat moderate-to-severe LUTS in men with a prostate volume of 30-80 mL. [strength rating: weak]” (Cornu et al., 2024)

Transurethral Waterjet Ablation or Aquablation

Transurethral Waterjet Ablation or Aquablation is a minimally invasive procedure intended for the treatment of LUTS resulting from BPH using high pressure saline jet for targeted and heat-free resection and removal of prostate tissue. The procedure is performed with live transrectal ultrasound.

Guidelines:

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80g. (Conditional Recommendation; Evidence Level: Grade C)” (Sandhu et al, 2023).

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer Aquablation* to patients with moderate-to-severe LUTS and a prostate volume of 30-80 mL as an alternative to transurethral resection of the prostate. [strength rating: weak]”
- “Inform patients about the risk of bleeding and the lack of long-term follow-up data. [strength rating: strong]” (Cornu et al., 2024)

The UroLift System

Urolift is a minimally invasive, prostatic urethral lift (PUL) system that provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen and reducing obstruction. Implants are delivered bilaterally to separate the encroaching lobes, beginning approximately 1.5 centimeters distal to the bladder neck. Cystoscopic inspection after each implant determines whether additional implants are required. Four to 5 implants are typically placed but this varies with the size and shape of the prostate. The device may avoid some of the morbidities and complications associated with other surgical approaches.

The UroLift System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hypertrophy (BPH) in men ≥ 45 years of age with a prostate size up to 80 milliliters (mL) in size whose symptoms are refractory to medical therapy, and/or who are inappropriate candidates for more invasive procedures or who do not wish to undergo these procedures. The procedure is typically performed by an urologist in the office or other outpatient setting with the use of local anesthesia and oral sedation. In December 2019, the FDA approved an expansion of indication for the UroLift System to include lateral and median lobe hyperplasia and a prostate volume up to 100 cc.

The L.I.F.T. Study randomized 206 patients with BPH to implantation of the UroLift device versus a sham procedure and met its primary endpoint finding that patients treated with the device had a $\geq 25\%$ reduction in the American Urological Association Symptom Index (AUASI) ($P < 0.0001$) at 3 months compared with the sham controls, which was sustained at 1 year. Other endpoints that were improved at 3 months and at 1 year in the UroLift group compared with the controls included the Benign Prostatic Hyperplasia Impact Index (BPHII) ($P < 0.001$ for both time points) and maximum urinary flow rate (Qmax) ($P < 0.0001$ for both time points). Changes in scores on the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), MSHQ-bother, and International Index of Erectile Function (IIEF-5) were similar between the UroLift group and the controls at 3 months and at 1 year. These clinical benefits were sustained through 2 years as shown by follow-up of 106 patients available for analysis.

Guidelines

American Urological Association - *Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023*

- “Prostatic urethral lift (PUL) should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g and verified absence of an obstructive middle lobe. (Moderate Recommendation; Evidence Level: Grade C)” (Sandhu et al, 2023)

European Association of Urology - *Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS) (2024)*

- “Offer prostatic urethral lift (Urolift®) to men with LUTS interested in preserving ejaculatory function, with prostates < 70 mL and no middle lobe.” (Cornu et al., 2024).

V. CODING INFORMATION

ICD-10 Codes that *may* apply:

N40.1 Enlarged prostate with lower urinary tract symptoms

CPT/HCPCS Codes:

- 52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
- 52442 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
- 53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (Rezüm)
- 0421T Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed) (*Not covered for Medicaid*)

Outpatient Facility Codes:

- C2596 Probe, image guided, robotic, waterjet ablation
- C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
- C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants
- L8699 Prosthetic implant, not otherwise specified

Not Covered

- 53850 Transurethral destruction of prostate tissue; by microwave thermotherapy
- 53852 Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
- 52282 Cystourethroscopy, with insertion of permanent urethral stent
- 0582T Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
- 0714T Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL
- 0867T Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
- 0941T Cystourethroscopy, flexible; with insertion and expansion of prostatic urethral scaffold using integrated cystoscopic visualization
- 0942T Cystourethroscopy, flexible; with removal and replacement of prostatic urethral scaffold
- 0943T Cystourethroscopy, flexible; with removal of prostatic urethral scaffold
- 51721 Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed
- 53865 Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate (*Covered for Medicaid and Medicare*)
- 53866 Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate (*Covered for Medicaid and Medicare*)
- 55881 Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation (*Covered for Medicaid and Medicare*)
- 55882 Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed (*Covered for Medicaid and Medicare*)

Prostatic Artery Embolization**ICD-10 Codes that may support medical necessity:**

- N40.1 Benign prostatic hyperplasia with lower urinary tract symptoms
- N40.3 Nodular prostate with lower urinary tract symptoms

CPT/HCPCS Codes:

- 37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
- 72191 Computed tomographic angiography, pelvis, with contrast material(s), including non-contrast images, if performed, and image postprocessing

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